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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

**FIRE et al.**

Appln. No. 09/215,257

Filed: December 18, 1998



Group Art Unit: 1632

Examiner: B. Campell

FOR: GENETIC INHIBITION BY DOUBLE-STRANDED RNA

\* \* \* \*

April 18, 2000

**REPLY TO RESTRICTION REQUIREMENT**

Hon. Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

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APR 19 2000  
TECH CENTER 1600/2900

Sir:

In response to the Office Action mailed March 29, 2000 (Paper No. 8), Applicants elect with traverse the claims of Group I, drawn to methods for inhibiting gene expression, for examination. This restriction requirement is based on incorrect assumptions and, when the claimed invention is properly understood, it is clear that rejoinder is appropriate because search and examination of the rejoined claims would not be unduly burdensome.

Firstly, as stated in the Action, claims included in both Groups I and II are generic (e.g., Claims 1-5, 10-18, 21-22, 28-31, 34 and 39). Limitation of the claims to either plant or animal organisms as sources of the cells is not recited in the generic claims. Thus, such generic claims must be searched and examined without regard to the source of the cells. In contrast to the assertion made in the Action ("the generic claims will be examined to the extent that they encompass the elected subject matter"), election of the claims of Group I requires examination of subject matter that is not restricted to animals because this is not a limitation recited in the generic claims. Similarly, the generic claim of Groups III and IV (i.e., Claim 36) does not recite a limitation on the source of the cell. Thus, at a minimum, the claims of Groups I and II (i.e., Claims 1-35 and 39) and Groups III and IV (i.e., Claims 36-38) should be rejoined.

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It appears to be the Examiner's position that examination of a generic claim may be restricted to subject matter (e.g., plants or animals) that is not recited as a limitation of the claim. If the claims of Groups I and II are not rejoined and examined on the merits in the next Action, Applicants respectfully request the Examiner provide support for his position in the Patent Statutes, regulations, or case law.

Secondly, examination of claims 1-39 in the same application would not be unduly burdensome because the inventive concept underlying these claims is the Applicants' unexpected discovery that double stranded RNA can be used to inhibit gene expression in a sequence dependent manner. The Examiner asserts that the claims of Groups I and II are distinct from those of Groups III and IV because "transient inhibition of gene expression is a different concept from production of transgenic organisms." Again, this statement makes an assumption about the claimed invention that is not a limitation recited in the claims. Here, it appears to be assumed that the claims of Groups I and II are limited to transient inhibition of gene expression, but this limitation is not recited in the claims. The claims are not limited to stable or transient inhibition of gene expression, but could include either embodiment of the invention. Thus, the assumed transience of the claimed methods is not a basis for finding that the claims are patentably distinct.

Reconsideration is respectfully requested. An understanding of the claimed invention as provided by completely reading the specification shows that inhibition of gene expression by double stranded RNA is the basis for all of the pending claims. Therefore, it would benefit both Applicants and the public interest to have all claims examined in the same application.

Thirdly, although transgenic animals and transgenic plants have been classified in separate subclasses, it is clear that a proper search of generic claims (e.g., Claims 1 and 36) would include both subclasses because the generic claims are not limited to animals or plants. It is applicants' prerogative to claim their invention in a manner that provides adequate patent protection. For example, Section 112 requires that applicants claim the subject matter which they regard as their invention. See M.P.E.P. § 608.01(k). There are no grounds to believe that the U.S. Patent and Trademark Office can override this

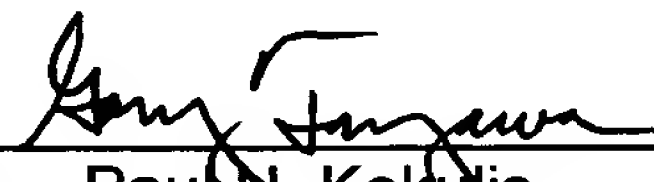
prerogative by restricting examination to the elected subject matter. Thus, there is no basis for the assertion that examination can be restricted (e.g., to either plants or animals, to either methods or cells/transgenic organisms) as though the subject matter defined by the Examiner is a limitation recited in the claims. If the Examiner should disagree, Applicants respectfully request that the next Action cite legal support for the proposition that the Examiner can unilaterally restrict the scope of patent protection provided by generic claims.

Finally, traversal is based on the ground that examination of claims 1-39 in a single application would not constitute an undue burden. Instead, this would benefit both Applicants and the public interest by expediting prosecution of the pending claims. At a minimum, the claims of Groups I and II should be rejoined because there is no basis in the law to confine examination to subject matter that is not recited as a limitation of the generic claims. Thus, Applicants submit that claims 1-39 should be examined together.

Examination on the merits is requested. If further information is required, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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